Chronic suppurative otitis media

Search date May 2010

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ABSTRACT

INTRODUCTION: Chronic suppurative otitis media (CSOM) is a common cause of hearing impairment and disability. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of treatments for chronic suppurative otitis media in adults and in children? What are the effects of treatments for cholesteatoma in adults and in children? We searched: Medline, Embase, The Cochrane Library, and other important databases up to May 2010 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 51 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review, we present information relating to the effectiveness and safety of the following interventions: topical ear cleansing, surgery for cholesteatoma, systemic antibiotics, topical antibiotics, topical antibiotics plus topical corticosteroids, topical antiseptics, topical corticosteroids, tympanoplasty (with or without mastoidectomy).

QUESTIONS

INTERVENTIONS

CSOM TREATMENT IN ADULTS

Likely to be beneficial

Unknown effectiveness

CSOM TREATMENT IN CHILDREN

Unknown effectiveness

CHOLESTEATOMA TREATMENT IN ADULTS

Unknown effectiveness

CHOLESTEATOMA TREATMENT IN CHILDREN

Unknown effectiveness

Covered elsewhere in Clinical Evidence

Acute otitis media

Otitis media with effusion

Key points

- Chronic suppurative otitis media (CSOM) causes recurrent or persistent discharge (otorrhoea) through a perforation in the tympanic membrane, and can lead to thickening of the middle-ear mucosa and mucosal polyps. It usually occurs as a complication of persistent acute otitis media with perforation in childhood.

  CSOM is a common cause of hearing impairment, disability, and poor scholastic performance. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries.

- In children with CSOM, topical antibiotics may improve symptoms compared with antiseptics. The benefits of ear cleansing are unknown, although this treatment is usually recommended for children with ear discharge.

- We don't know whether topical antiseptics, topical or systemic antibiotics, or topical corticosteroids, alone or in combination with antibiotics, improve symptoms in children with CSOM compared with placebo or other treatments.

- In adults with CSOM, topical antibiotics either alone or in combination with topical corticosteroids may improve symptoms compared with placebo or either treatment alone, although we found few adequate studies. There is consensus that topical antibiotics should be combined with ear cleansing so that the antibiotics are able to reach the middle ear space.

  We don't know whether topical antiseptics, topical corticosteroids, or systemic antibiotics are beneficial in reducing symptoms.

  It is possible that antibiotics against gram-negative bacteria may reduce ear discharge more than other classes of antibiotics or placebo.
- We don't know whether tympanoplasty with or without mastoidectomy improves symptoms compared with no surgery or other treatments in adults or children with CSOM.
- Cholesteatoma is an abnormal accumulation of squamous epithelium usually found in the middle ear cavity and mastoid process of the temporal bone. Granulation tissue and ear discharge are often associated with secondary infection of the desquamating epithelium.
- Cholesteatoma can be either congenital (behind an intact tympanic membrane) or acquired. If untreated, it may progressively enlarge and erode the surrounding structures.

  We don't know the beneficial effects of surgery, whether surgery can be delayed, or which surgical techniques are associated with the best outcomes in children or adults with cholesteatoma.

DEFINITION

Chronic suppurative otitis media (CSOM) is persistent inflammation of the middle ear or mastoid cavity. Synonyms include "chronic otitis media", chronic mastoiditis, and chronic tympanomastoiditis. CSOM is characterised by recurrent or persistent ear discharge (otorrhoea) over 2 to 6 weeks through a perforation of the tympanic membrane. CSOM usually begins as a complication of persistent acute otitis media (AOM) with perforation in childhood. Typical findings may also include thickened granular middle-ear mucosa and mucosal polyps. Occasionally, CSOM will be associated with a cholesteatoma within the middle ear. CSOM is differentiated from chronic otitis media with effusion, in which there is an intact tympanic membrane with fluid in the middle ear but no active infection. CSOM does not include chronic perforations of the eardrum that are dry, or only occasionally discharge, and have no signs of active infection. Cholesteatoma is an abnormal accumulation of squamous epithelium usually found in the middle ear cavity and mastoid process of the temporal bone. Granulation tissue and ear discharge are often associated with secondary infection of the desquamating epithelium. Cholesteatoma is most often detected by careful otoscopic examination in children or adults with persistent discharge that does not respond to treatment.

INCIDENCE/ PREVALENCE

The worldwide prevalence of CSOM is 65 to 330 million people, and 39 to 200 million (60%) have clinically significant hearing impairment. [1] Cholesteatoma can be either congenital (behind an intact tympanic membrane) or acquired. The overall incidence is estimated to be around 9 per 100,000 people. At least 95% of cholesteatomas are acquired. The incidence is similar in children and adults. [2]

AETIOLOGY/ RISK FACTORS

CSOM is usually a complication of persistent AOM, but the risk factors for CSOM vary in different settings. Frequent upper respiratory tract infections and poor socioeconomic conditions (overcrowded housing [3] [4] and poor hygiene and nutrition [4]) are often associated with the development of CSOM. [5] [6] In developed countries and advantaged populations, previous insertion of tympanostomy tubes is now probably the single most important aetiological factor. [7] Of those children with tympanostomy tubes in place, a history of recurrent AOM, older siblings, and attendance at child care centres all increase the risk of developing CSOM. [7] In developing countries and disadvantaged populations, poverty, overcrowding, family history, exposure to smoke, and being Indigenous are important. [4] [8] [9] Improvement in housing, hygiene, and nutrition in Maori children was associated with a halving of the prevalence of CSOM between 1978 and 1987 [10] (see also review on acute otitis media). The most commonly isolated microorganisms are *Pseudomonas aeruginosa* and *Staphylococcus aureus*; [11] *P aeruginosa* has been particularly implicated in the causation of bony necrosis and mucosal disease. One systematic review found a lack of studies assessing the role of prophylactic antibiotics in preventing the progression of disease to CSOM. [12] Most cholesteatomas are thought to occur as a complication of a retraction pocket in the tympanic membrane. They are associated with recurrent or persistent middle ear disease, family history, and craniofacial abnormalities. If untreated, a cholesteatoma may progressively enlarge and erode the surrounding structures. [2]

PROGNOSIS

The natural history of CSOM is poorly understood. The perforation may close spontaneously in an unknown portion of cases, but it persists in others leading to mild to moderate hearing impairment (about 26–60 dB increase in hearing thresholds), based on surveys among children in Africa, Brazil, [13] India, [14] and Sierra Leone, [15] and among the general population in Thailand. [16] In many developing countries, CSOM represents the most frequent cause of moderate hearing loss

(40–60 dB). [17] Persistent hearing loss during the first 2 years of life may increase learning disabilities and poor scholastic performance. [18] Progressive hearing loss may occur among those in whom infection persists and discharge recurs. Less frequently, spread of infection may lead to life-threatening complications such as intracranial infections and acute mastoiditis. [19] The frequency of serious complications fell from 20% in 1938 to 2.5% in 1948 worldwide and is currently estimated to be about 0.7% to 3.2% worldwide. [11] This is believed to be associated with increased use of antibiotic treatment, tympanoplasty, and mastoidectomy. [20] [21] [22] Otitis media was estimated to have caused 3599 deaths and a loss of almost 1.5 disability-adjusted life years in 2002, 90% of which were in developing countries. [23] Most of these deaths were probably owing to CSOM, because AOM is a self-limiting infection (see review on acute otitis media).

AIMS OF INTERVENTION

To improve symptoms of otorrhoea; heal perforations; improve hearing; and reduce complications, with minimum adverse effects of treatment.

OUTCOMES

Death; reduction in otorrhoea: proportion of people with otorrhoea measured subjectively or by otoscopy; with tympanic perforation; hearing loss; intra- and extracranial complications; duration of otorrhoea-free periods. The correlation between subjective cessation of otorrhoea and otoscopic findings was poor in one RCT. [24] Many RCTs used compound outcomes denoting otoscopic activity (i.e., otorrhoea or inflammation in the middle ear). **Hearing:** severity of hearing loss; **intra- and extracranial complications; adverse effects of treatment.**

METHODS

Clinical Evidence search and appraisal May 2010. Studies that included both adults (aged 16 years or older) and children (aged 10 years or younger) or which failed to specify the age of participants were excluded from the benefits section. However, we have included harms data from systematic reviews that included both adults and children. The RCTs varied in their definitions of CSOM and measurements of severity. Most RCTs were brief (7 days to 4 weeks). Most had inadequate methods from which to draw reliable conclusions (see main text for descriptions). Participants with cholesteatoma were excluded from most, but not all, trials of treatments for CSOM. All trials excluded people with impending serious complications. The following databases were used to identify studies for this systematic review: Medline 1966 to May 2010; Embase 1980 to May 2010; and The Cochrane Database of Systematic Reviews 2010, Issue 2 (1966 to April 2010). An additional search within The Cochrane Library was carried out for the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment (HTA) database. We also searched for retractions of studies included in the review. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the contributor for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews of RCTs and RCTs in any language, and containing >20 individuals. There was no minimum length of follow-up required to include studies. We included systematic reviews of RCTs and RCTs where harms of an included intervention were studied applying the same study design criteria for inclusion as we did for benefits. In addition we did an observational harms search for ototoxicity of topical antibiotics and topical antiseptics as highlighted by the contributor. We searched for prospective and retrospective cohort and case series studies of at least 20 individuals. In addition we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the MHRA, which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 44). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the Clinical Evidence population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION What are the effects of treatments for chronic suppurative otitis media in adults?

OPTION ANTIBIOTICS (TOPICAL) PLUS CORTICOSTEROIDS (TOPICAL) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- Topical antibiotics in combination with topical corticosteroids may improve symptoms compared with placebo or either treatment alone in adults, although we found few adequate studies.

Benefits and harms

Topical antibiotics plus topical corticosteroids versus placebo:

We found two RCTs. [24] [25]

Reduction in otorrhoea

Compared with placebo Topical antibiotics plus topical corticosteroids (gentamicin plus hydrocortisone) may be more effective at reducing persistent otorrhoea as determined by otoscopy in adults with chronic suppurative otitis media (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[24] RCT	123 adults with chronic suppurative otitis media (CSOM), no cholesteatoma, and no open mastoid cavity	**Proportion of people with otoscopically active otitis media** 33/64 (52%) with topical gentamicin plus hydrocortisone (if compliance to medication was >70%) 44/59 (75%) with placebo	P <0.05	○○○	gentamicin plus hydrocortisone
[25] RCT Published only as an abstract	31 adults	**Proportion of people with active otitis media on otoscopy , 4 weeks** 6/17 (35%) with topical gentamicin plus hydrocortisone 11/14 (79%) with placebo	OR 0.18 95% CI 0.05 to 0.75	●●●	gentamicin plus hydrocortisone

Hearing

No data from the following reference on this outcome. [24] [25]

Intra- and extracranial complications

No data from the following reference on this outcome. [24] [25]

Death

No data from the following reference on this outcome. [24] [25]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[24] RCT	123 adults with chronic suppurative otitis media (CSOM), no cholesteatoma, and no open mastoid cavity	**Neurological adverse effects** with topical gentamicin plus hydrocortisone (if compliance to medication was >70%) with placebo Absolute results not reported			

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		No increased incidence of tinnitus or vertigo with topical gentamicin plus hydrocortisone ear drops			

No data from the following reference on this outcome. [25]

Topical antibiotics plus topical corticosteroids versus topical corticosteroids alone:

We found one RCT comparing topical gentamicin plus hydrocortisone versus betamethasone. [26]

Reduction in otorrhoea

Compared with topical corticosteroids alone Topical antibiotics plus topical corticosteroids (gentamicin plus hydrocortisone) may be more effective than the topical corticosteroid betamethasone at 3 weeks at reducing the proportion of people with persistent activity on otoscopy (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[26] RCT	64 adults	**Proportion of people with persistent activity on otoscopy , 3 weeks** 6/30 (20%) with topical gentamicin plus hydrocortisone 17/24 (71%) with topical betamethasone	RR 0.28 95% CI 0.13 to 0.60 NNT 2 95% CI 2 to 4	●●○	gentamicin plus hydrocortisone

Hearing

No data from the following reference on this outcome. [26]

Intra- and extracranial complications

No data from the following reference on this outcome. [26]

Death

No data from the following reference on this outcome. [26]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[26]	64 adults	**Adverse effects**			

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
RCT		with topical gentamicin–hydrocortisone with topical betamethasone Absolute results not reported 1 person stopped treatment with gentamicin plus hydrocortisone drops because of experiencing a burning sensation, but no allergic reactions were reported (no further data reported)			
[27] RCT	150 people with chronic otitis media	**Ototoxicity: mean difference in sensorineural hearing threshold (dB) , 1.5 years** 6.0 dB with neomycin plus polymyxin B plus dexamethasone –0.9 dB with dexamethasone alone	P <0.025	○○○	dexamethasone

Topical antibiotics plus topical corticosteroids versus topical antibiotics alone:
We found two RCTs. [28] [29]

Reduction in otorrhoea

Compared with topical antibiotics alone We don't know whether topical antibiotics plus topical corticosteroids are more effective at increasing clinical response rates (not further defined) in adults with chronic suppurative otitis media (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[28] RCT **4-armed trial** Data from English abstract only	80 adults, aged 18 to 60 years, 103 ears, Turkey	**Clinical response** 80% with topical ciprofloxacin 70% with topical tobramycin 90% with topical ciprofloxacin plus dexamethasone 75% with topical tobramycin plus dexamethasone Absolute numbers not reported The RCT did not state how clinical response or recovery were defined (see further information on studies)	P >0.03 among groups	⟷	Not significant
[29] RCT	322 adults, aged 14 to 71 years, Spain	**Cure rates , 6 to 12 days' treatment** 117/154 (76%) with topical polymyxin B–neomycin–hydrocortisone 146/168 (87%) with topical ciprofloxacin Intention-to-treat (ITT) analysis	ARR −11% 90% CI −16.43% to −5.21% (ITT)	○○○	topical ciprofloxacin

Hearing

No data from the following reference on this outcome. [28] [29]

Intra- and extracranial complications

No data from the following reference on this outcome. [28] [29]

Death

No data from the following reference on this outcome. [28] [29]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[29] RCT	322 adults, aged 14 to 71 years, Spain	**Deterioration of the audiogram, 6 to 12 days** 0/157 (0%) with topical ciprofloxacin 1/138 (1%) with topical polymyxin-B plus neomycin plus hydrocortisone	OR 0.12 95% CI 0.002 to 5.99 The clinical importance of this difference is unclear	⟷	Not significant
[29] RCT	322 adults, aged 14 to 71 years, Spain	**Proportion of people with adverse effects** 24/165 (15%) with topical ciprofloxacin 12/153 (8%) with topical polymyxin-B plus neomycin plus hydrocortisone Vertigo was reported by 2 people using topical ciprofloxacin and by none using topical polymyxin-B plus neomycin plus hydrocortisone	RR 1.86 95% CI 0.96 to 3.60	⟷	Not significant

No data from the following reference on this outcome. [28]

Further information on studies

[24] Similar results were found in 42 other people who had an open mastoid cavity.

[26] The RCT did not state whether the assessment of outcomes was double blind. No intention-to-treat analysis was performed.

[28] There were only limited data from the RCT, as only the abstract was reported in English, and it did not state how clinical response or recovery were defined.

Comment: See comment on topical antibiotics in adults, p 17 . There is a lack of good evidence to support the benefit of topical antibiotics plus topical corticosteroids with confidence.

OPTION ANTIBIOTICS (SYSTEMIC) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether systemic antibiotics are beneficial in reducing symptoms.

Benefits and harms

Systemic antibiotics versus placebo:

We found no systematic review or RCTs investigating the effects of systemic antibiotics compared with placebo in adults receiving no other treatment.

Systemic antibiotics versus topical antibiotics:

We found one systematic review (search date 2005), [30] which identified 5 RCTs in adults. [31] [32] [33] [34] [35]

Reduction in otorrhoea

Compared with topical antibiotics Systemic antibiotics seem less effective at reducing persistent otorrhoea at 1 to 2 weeks in adults (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[30] Systematic review	116 people 2 RCTs in this analysis	**Persistent otorrhoea , 1 to 2 weeks** 37/57 (65%) with systemic non-quinolones 12/59 (20%) with topical quinolones	RR 3.21 95% CI 1.88 to 5.49	●●○	topical antibiotics
[31] RCT **3-armed trial**	75 adults randomised, 51 adults analysed, Scottish hospital clinic In review [30] The remaining arm assessed topical antiseptics (boric acid and iodine powder plus ear cleansing under microscopic vision)	**Persistent otorrhoea , 4 weeks** 8/13 (62%) with systemic antibiotic (cefalexin, flucloxacillin, cloxacillin, or amoxicillin) 15/18 (83%) with topical antibiotic (gentamicin or chloramphenicol)	RR for systemic *v* topical antibiotic 0.74 95% CI 0.46 to 1.19	⟷	Not significant
[32] RCT **3-armed trial**	60 adults, 5 to 10 days' treatment In review [30] The remaining arm assessed combined treatment with oral (250 mg twice daily) plus topical (250 micrograms/mL, 3 drops twice daily) ciprofloxacin	**Proportion of people with persistent otorrhoea , 1 to 2 weeks** 12/20 (60%) with oral ciprofloxacin (250 mg twice daily) 3/20 (15%) with topical ciprofloxacin (250 micrograms/mL, 3 drops twice daily)	RR for oral *v* topical ciprofloxacin 4.00 95% CI 1.33 to 12.05	●●○	topical ciprofloxacin
[33] RCT	60 adults, 5 to 10 days' treatment In review [30]	**Persistent otorrhoea , 1 to 2 weeks** 17/30 (57%) with intramuscular gentamicin 5/30 (17%) with topical ciprofloxacin	RR for intramuscular gentamicin *v* topical ciprofloxacin 3.40 95% CI 1.44 to 8.03	●●○	topical ciprofloxacin

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[34] RCT	60 adults, 10 days' treatment In review [30]	**Persistent otorrhoea , 1 to 2 weeks** 15/30 (50%) with oral ciprofloxacin 5/30 (17%) with topical ciprofloxacin	RR 3.00 95% CI 1.25 to 7.21	●●○	topical ciprofloxacin
[35] RCT	60 adults, 7 days' treatment In review [30]	**Persistent otorrhoea , 1 to 2 weeks** 20/27 (74%) with oral amoxicillin–clavulanic acid (co-amoxiclav) 7/29 (24%) with topical ofloxacin	RR 3.07 95% CI 1.55 to 6.07	●●○	topical ofloxacin

Hearing

No data from the following reference on this outcome. [30]

Intra- and extracranial complications

No data from the following reference on this outcome. [30]

Death

No data from the following reference on this outcome. [30]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[31] RCT **3-armed trial**	75 adults randomised, 51 adults analysed, Scottish hospital clinic In review [30] The remaining arm assessed topical antiseptics (boric acid and iodine powder plus ear cleansing under microscopic vision)	**Adverse effects** with systemic antibiotic (cefalexin, flucloxacillin, cloxacillin, or amoxicillin) with topical antibiotic (gentamicin or chloramphenicol) No adverse effects reported with systemic antibiotic (cefalexin, flucloxacillin, cloxacillin, or amoxicillin) or topical antibiotic (gentamicin or chloramphenicol)			
[33] RCT	60 adults, 5 to 10 days' treatment In review [30]	**Adverse effects** with intramuscular gentamicin with topical ciprofloxacin No adverse effects were reported with topical ciprofloxacin and audiometric functioning did not			

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		worsen during treatment. No data for intramuscular gentamicin			
[35] RCT	60 adults, 7 days' treatment In review [30]	**Audiometric functioning** with oral amoxicillin–clavulanic acid (co-amoxiclav) with topical ofloxacin No changes in audiometric functioning before or after treatment were reported with oral amoxicillin–clavulanic acid or topical ofloxacin			

No data from the following reference on this outcome. [34]

Systemic antibiotics versus topical antiseptics:

We found one systematic review [30] (search date 2005; 1 RCT [31]). The RCT compared three treatments: oral antibiotics, topical antiseptics, and topical antibiotics). [31]

Reduction in otorrhoea

Compared with topical antiseptics Oral antibiotics and topical antiseptics seem equally effective (or ineffective) at reducing the rate of persistent activity on otoscopy (persistent discharge) at 2 to 4 weeks in adults (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[31] RCT **3-armed trial**	75 adults randomised, 51 adults analysed, Scottish hospital clinic In review [30] The remaining arm assessed topical antibiotic (gentamicin or chloramphenicol)	**Rate of persistent activity on otoscopy (persistent discharge) , 2 to 4 weeks** 8/13 (62%) with oral antibiotics (cefalexin, flucloxacillin, cloxacillin, or amoxicillin) 13/20 (65%) with topical antiseptics (boric acid and iodine powder plus ear cleansing under microscopic vision)	RR for oral antibiotic *v* topical antiseptic 0.95 95% CI 0.55 to 1.62 The RCT may have been underpowered to detect a clinically important difference between groups	⟷	Not significant

Hearing

No data from the following reference on this outcome. [30] [31]

Intra- and extracranial complications

No data from the following reference on this outcome. [30] [31]

Death

No data from the following reference on this outcome. [30] [31]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[30] Systematic review	Adults with chronic suppurative otitis media	**Adverse effects** with oral antibiotics; with topical antiseptics; Absolute results not reported; Negligible or no changes in hearing acuity reported with topical antiseptics			

Systemic antibiotics versus each other:
We found three RCTs. [36] [37] [38]

Reduction in otorrhoea

Compared with each other We don't know which systemic antibiotic is more effective at reducing persistent otorrhoea in adults (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[36] RCT	76 people	**Proportion of people with resolution of otorrhoea , 10 days' treatment**; 24/40 (60%) with oral ciprofloxacin (500 mg twice daily); 13/35 (37%) with amoxicillin–clavulanic acid (co-amoxiclav; 500 mg three times daily)	P = 0.04	○○○	oral ciprofloxacin
[37] RCT	190 adults	**Persistent otoscopic abnormality , 10 days' treatment**; 37/94 (39%) with oral cefotiam hexetil; 33/94 (35%) with amoxicillin–clavulanic acid	P = 0.55	⟷	Not significant
[38] RCT	30 adults, 22 analysed	**Resolution of otorrhoea , 10 days' treatment**; 9/12 (75%) with oral levofloxacin (500 mg once daily); 6/10 (60%) with oral amoxicillin–clavulanic acid (675 mg three times daily)	P = 0.05; Borderline significance	○○○	oral levofloxacin

Hearing

No data from the following reference on this outcome. [36] [37] [38]

Intra- and extracranial complications

No data from the following reference on this outcome. [36] [37] [38]

Death

No data from the following reference on this outcome. [36] [37] [38]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[36] RCT	76 people	**Diarrhoea, nausea, abdominal pain, and headache** 10% with oral ciprofloxacin 14% with oral amoxicillin–clavulanic acid (co-amoxiclav) Absolute numbers not reported			
[37] RCT	190 adults	**Gastrointestinal adverse effects (abdominal pain, diarrhoea, and flatulence)** 13/95 (14%) with oral cefotiam 34/95 (36%) with amoxicillin–clavulanic acid	P = 0.001	○○○	cefotiam
[38] RCT	30 adults, 22 analysed	**Adverse effects** with oral levofloxacin (500 mg once daily) with oral amoxicillin–clavulanic acid (675 mg three times daily) Absolute results not reported The RCT reported no adverse effects associated with either intervention			

Systemic antibiotics added to mastoidectomy or tympanoplasty:

We found one RCT, comparing preoperative intravenous ceftazidime (2 g 12 hours preoperatively and 1–2 g 8-hourly for 5 days postoperatively) with no antibiotic. [39]

Reduction in otorrhoea

Systemic antibiotics added to mastoidectomy or tympanoplasty compared with no antibiotic Preoperative intravenous ceftazidime may be more effective at reducing the proportion of people with otorrhoea on otoscopy at 2 months in adults having mastoidectomy or tympanoplasty (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[39] RCT	26 adults having mastoidectomy/tympanoplasty Although randomisation was thorough, groups are likely to have been unbalanced for baseline severity, with more people in the antibiotic arm having only tympanoplasty	**Proportion of people with otorrhoea on otoscopy or with positive *Pseudomonas aeruginosa* cultures , 2 months** 1/14 (7%) with intravenous ceftazidime 7/12 (58%) with no antibiotic	P = 0.01	○○○	intravenous ceftazidime

Hearing

No data from the following reference on this outcome. [39]

Intra- and extracranial complications

No data from the following reference on this outcome. [39]

Death

No data from the following reference on this outcome. [39]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[39] RCT	26 adults having mastoidectomy/tympanoplasty Although randomisation was thorough, groups are likely to have been unbalanced for baseline severity, with more people in the antibiotic arm having only tympanoplasty	**Adverse effects** with intravenous ceftazidime with no antibiotic Absolute results not reported No adverse effects reported with ceftazidime			

Systemic antibiotics versus topical antibiotics plus systemic antibiotics:

See option on topical antibiotics plus systemic antibiotics in adults, p 14 .

Further information on studies

[30] The topical antibiotics used were ofloxacin, ciprofloxacin, gentamicin, and chloramphenicol. The systemic antibiotics were oral cefalexin, flucloxacillin, cloxacillin, amoxicillin, ciprofloxacin, amoxicillin–clavulanic acid (co-amoxiclav), and intramuscular gentamicin.

[36] [37] [38] None of the RCTs reported changes in hearing as measured by pure tone audiometry.

Comment: None.

OPTION ANTIBIOTICS (TOPICAL PLUS SYSTEMIC) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We found no direct information from RCTs about whether topical plus systemic antibiotics are better than no active treatment in adults with chronic suppurative otitis media.
- Antibiotics against gram-negative bacteria may reduce ear discharge more than other classes of antibiotics or placebo.

Benefits and harms

Topical plus systemic antibiotics versus placebo:

We found no systematic review or RCTs comparing topical plus systemic antibiotics versus placebo in adults.

Topical plus systemic antibiotics versus topical antibiotics alone:

We found three RCTs. [32] [40] [41] The first RCT compared three treatments: oral ciprofloxacin, topical ciprofloxacin, and oral plus topical ciprofloxacin. [32] The second RCT compared topical gentamicin–hydrocortisone (for 4 weeks) with and without oral metronidazole given for 2 weeks. [40] The third RCT compared topical plus oral non-quinolone antibiotics versus topical quinolone antibiotics alone. [41] See option on topical antibiotics in adults, p 17 and option on systemic antibiotics in adults, p 8 for further information on adverse effects.

Reduction in otorrhoea

Compared with topical antibiotics alone We don't know whether systemic antibiotics plus topical antibiotics are more effective at reducing otorrhoea at 2 weeks (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[32] RCT **3-armed trial**	60 adults The remaining arm assessed oral ciprofloxacin (250 mg twice daily) alone	**Proportion of people with otorrhoea , 2 weeks** 5/20 (25%) with topical (250 micrograms/mL, 3 drops twice daily) plus oral (250 mg twice daily) ciprofloxacin given for 5 to 10 days 3/20 (15%) with topical ciprofloxacin (250 micrograms/mL, 3 drops twice daily) given for 5 to 10 days	RR for topical plus oral ciprofloxacin *v* topical ciprofloxacin alone 1.67 95% CI 0.46 to 6.06	⟷	Not significant
[40] RCT	30 adults	**Otorrhoea , end of treatment** 6/14 (43%) with topical gentamicin–hydrocortisone (for 4 weeks) plus oral metronidazole (given for 2 weeks)	Significance assessment between groups not reported		

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		6/16 (38%) with topical gentamicin–hydrocortisone (for 4 weeks) alone			
[41] RCT	80 adults, 89 ears The RCT randomised people but analysed the number of ears with persistent otorrhoea	**Proportion of ears exhibiting persistent signs (ear pain, discharge, or inflammation on otoscopic examination) , 2 weeks** 33% with topical (0.3%) ofloxacin 63% with oral amoxicillin plus topical chloramphenicol Absolute numbers not reported Number of ears examined not reported	P <0.001	○○○	topical ofloxacin

Hearing

No data from the following reference on this outcome. [32] [40] [41]

Intra- and extracranial complications

No data from the following reference on this outcome. [32] [40] [41]

Death

No data from the following reference on this outcome. [32] [40] [41]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[32] RCT **3-armed trial**	60 adults The remaining arm assessed oral ciprofloxacin (250 mg twice daily) alone	**Adverse effects** with topical (250 micrograms/mL, 3 drops twice daily) plus oral (250 mg twice daily) ciprofloxacin given for 5 to 10 days with topical ciprofloxacin (250 micrograms/mL, 3 drops twice daily) given for 5 to 10 days Absolute results not reported Audiometric functioning did not worsen during treatment with combined oral plus topical ciprofloxacin or topical ciprofloxacin alone and no adverse effects were reported			
[41]	80 adults, 89 ears	**Adverse effects**			

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
RCT	The RCT randomised people but analysed the number of ears with persistent otorrhoea	with topical (0.3%) ofloxacin with oral amoxicillin plus topical chloramphenicol Absolute results not reported Ototoxicity (defined as an elevation in bone conduction thresholds, speech reception thresholds of 5 dB or more, or both) was reported with amoxicillin–chloramphenicol but not with ofloxacin			

No data from the following reference on this outcome. [40]

Topical antibiotics plus systemic antibiotics versus systemic antibiotics alone:

We found two RCTs. [32] [42] The first RCT compared three treatments: topical ciprofloxacin alone, oral ciprofloxacin alone, or topical plus oral ciprofloxacin. [32] The second RCT compared topical ceftizoxime versus sodium chloride solution among people who were given intramuscular ceftizoxime for 7 days. [42]

Reduction in otorrhoea

Compared with systemic antibiotics alone We don't know whether topical antibiotics plus systemic antibiotics are more effective at increasing discharge resolution in adults (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[32] RCT **3-armed trial**	60 adults The remaining arm assessed topical ciprofloxacin (250 micrograms/mL, 3 drops twice daily) alone	**Discharge resolution** 15/20 (75%) with topical (250 micrograms/mL, 3 drops twice daily) plus oral (250 mg twice daily) ciprofloxacin 8/20 (40%) with oral ciprofloxacin (250 mg twice daily) alone	P <0.05 for topical plus oral ciprofloxacin *v* oral ciprofloxacin alone	○○○	topical ciprofloxacin plus oral ciprofloxacin
[42] RCT	248 adults	**Improvement of symptoms and otoscopic findings , 7 days' treatment** 96% with topical ceftizoxime (2 g/day) plus intramuscular ceftizoxime 93% with topical 0.9% sodium chloride plus intramuscular ceftizoxime Absolute numbers not reported	Reported as not significant P value not reported	⟷	Not significant

Hearing

No data from the following reference on this outcome. [32] [42]

Intra- and extracranial complications

No data from the following reference on this outcome. [32] [42]

Death

No data from the following reference on this outcome. [32] [42]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[32] RCT **3-armed trial**	60 adults The remaining arm assessed topical ciprofloxacin (250 micro-grams/mL, 3 drops twice daily) alone	**Adverse effects** with topical (250 micrograms/mL, 3 drops twice daily) plus oral (250 mg twice daily) ciprofloxacin with oral ciprofloxacin (250 mg twice daily) alone Absolute results not reported "Audiometric functioning did not worsen" during treatment and no adverse effects were reported			
[42] RCT	248 adults	**Adverse effects (skin rash, di-arrhoea, and epigastralgia)** 0.8% with combined topical plus systemic antibiotics 1.6% with systemic antibiotics alone Absolute numbers not reported	Significance assessment not re-ported		

Further information on studies

Comment: **Clinical guide**

The difference in the results of the three RCTs comparing topical plus systemic antibiotics versus topical antibiotics alone may be because of the spectrums of antibiotics being compared. When antibiotics of the same class were compared, [32] addition of systemic antibiotics to topical antibiotics did not seem to produce any added benefit. By contrast, a topical quinolone antibiotic was found to be more effective than topical plus oral non-quinolones. [41] This suggests that drugs against gram-negative bacteria, particularly *Pseudomonas aeruginosa*, may be particularly effective in re-ducing otorrhoea. The same might be true regarding the lack of benefit of adding topical to systemic antibiotics of the same class. [42]

OPTION ANTIBIOTICS (TOPICAL) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- Topical antibiotics may improve symptoms compared with placebo or no treatment in adults, although we found few adequate studies. There is consensus that topical antibiotics should be combined with ear cleansing.
- Vestibular ototoxicity has been reported following the use of topical non-quinolone antibiotics.

Benefits and harms

Topical antibiotics versus placebo:

We found one systematic review (search date 2005), [43] which identified one RCT comparing topical antibiotics alone versus placebo in adults. [32] All participants received ear cleansing.

Reduction in otorrhoea

Compared with placebo Topical ciprofloxacin may be more effective at reducing persistent otorrhoea at 7 days in adults with chronic suppurative otitis media (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[32] RCT	50 adults with chronic suppurative otitis media but no cholesteatoma in a hospital clinic in Thailand In review [43]	**Persistent otorrhoea on otoscopic examination , 7 days** 3/19 (16%) with topical ciprofloxacin in 0.9% sodium chloride (5 drops 0.25 g/L three times daily for 7 days) 14/16 (88%) with 0.9% sodium chloride alone All participants received ear cleansing	RR 0.18 95% CI 0.06 to 0.52 NNT 2 95% CI 2 to 3	●●●	topical ciprofloxacin

Hearing

No data from the following reference on this outcome. [43] [32]

Intra- and extracranial complications

No data from the following reference on this outcome. [43] [32]

Death

No data from the following reference on this outcome. [43] [32]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[32] RCT	50 adults with chronic suppurative otitis media but no cholesteatoma in a hospital clinic in Thailand In review [43]	**Adverse effects** with topical ciprofloxacin in 0.9% sodium chloride (5 drops 0.25 g/L three times daily for 7 days) with 0.9% sodium chloride alone Absolute results not reported Audiometric functioning did not worsen during treatment and no adverse effects were reported			

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		All participants received ear cleansing			

Topical antibiotics versus each other:

We found one systematic review (search date 2005; 5 RCTs). [43]

Reduction in otorrhoea

Compared with each other Topical quinolones and topical non-quinolones seem equally effective at 1 week and 3 weeks at reducing persistent discharge in adults with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[43] Systematic review	402 adults 3 RCTs in this analysis	**Rate of persistent discharge , 1 week** 25/193 (13%) with topical quinolone (ciprofloxacin) 43/209 (21%) with topical non-quinolone (gentamicin or tobramycin)	RR 0.89 95% CI 0.59 to 1.32	⟷	Not significant
[43] Systematic review	77 adults 2 RCTs in this analysis	**Rate of persistent discharge , 3 weeks** 14/39 (36%) with topical quinolone (ciprofloxacin) 14/38 (37%) with topical non-quinolone (gentamicin or tobramycin)	RR 0.97 95% CI 0.54 to 1.72	⟷	Not significant
[44] RCT	100 people in this analysis In review [43]	**Proportion of people who still had a wet ear on otoscopy , end of treatment** 8/50 (16%) with topical trimethoprim–sulfacetamide–polymyxin B 4/50 (8%) with topical gentamicin	RR 2.00 95% CI 0.64 to 6.22	⟷	Not significant
[45] RCT	68 people in this analysis In review [43]	**Proportion of people who still had a wet ear on otoscopy , end of treatment** 4/35 (11%) with topical trimethoprim–sulfacetamide–polymyxin B 13/33 (39%) with topical trimethoprim–polymyxin B	RR 0.29 95% CI 0.11 to 0.80	●●○	topical trimethoprim–sulfacetamide–polymyxin B

Hearing

No data from the following reference on this outcome. [43]

Intra- and extracranial complications

No data from the following reference on this outcome. [43]

Death

No data from the following reference on this outcome. [43]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[43] Systematic review	Adults with chronic suppurative otitis media 3 RCTs in this analysis	**Adverse effects** with different topical antibiotics versus each other Absolute results not reported The systematic review found that the rates of minor adverse effects reported in RCTs were low and did not vary appreciably among antibiotics Minor adverse effects included *Candida* infections, dizziness, itching, stinging, and earache			

Topical antibiotics versus systemic antibiotics:

See option on systemic antibiotics in adults, p 8 .

Topical antibiotics versus topical antiseptics:

We found one systematic review [43] (search date 2005, 2 RCTs [31] [46]).

Reduction in otorrhoea

Topical antibiotics compared with topical antiseptics We don't know whether topical antibiotics are more effective at reducing evidence of infection on otoscopy (persistent discharge) at 2 to 4 weeks in adults with chronic suppurative otitis media (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[31] RCT **3-armed trial**	75 adults randomised, 51 adults analysed In review [43] The remaining arm assessed oral antibiotics (cefalexin, flucloxacillin, cloxacillin, or amoxicillin, according to bacterial sensitivity)	**Persistent activity on otoscopy (persistent discharge) , 2 to 4 weeks** 15/18 (83%) with topical antibiotics (gentamicin or chloramphenicol) 13/20 (65%) with topical antiseptics (boric acid and iodine powder plus ear cleansing under microscopic vision)	RR for topical antibiotics *v* topical antiseptics 1.28 95% CI 0.87 to 1.88 The RCT may have been underpowered to detect a clinically important difference between groups	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[46] RCT **3-armed trial**	51 adults with chronic suppurative otitis media (CSOM) without cholesteatoma in a hospital clinic in Israel; 60 ears In review [43] The remaining arm assessed topical tobramycin The RCT randomised people to treatments, but presented results in terms of number of ears	**Proportion of people with unimproved otorrhoea , 3 weeks' treatment** 4/19 (21%) with topical ciprofloxacin 10/17 (59%) with diluted antiseptic solution (1% aluminium acetate)	P = 0.02 for ciprofloxacin *v* placebo	○○○	topical ciprofloxacin
[46] RCT **3-armed trial**	51 adults with CSOM without cholesteatoma in a hospital clinic in Israel; 60 ears In review [43] The remaining arm assessed topical ciprofloxacin The RCT randomised people to treatments, but presented results in terms of number of ears	**Proportion of people with unimproved otorrhoea , 3 weeks' treatment** 5/18 (28%) with topical tobramycin 10/17 (59%) with diluted antiseptic solution (1% aluminium acetate)	P = 0.06 for tobramycin *v* placebo	⟷	Not significant

Hearing

No data from the following reference on this outcome. [43] [31] [46]

Intra- and extracranial complications

No data from the following reference on this outcome. [43] [31] [46]

Death

No data from the following reference on this outcome. [43] [31] [46]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[43] Systematic review **3-armed trial**	Adults with chronic suppurative otitis media 2 RCTs in this analysis	**Adverse effects** with different topical antibiotics versus each other Absolute results not reported The review found negligible or no changes in hearing acuity after topical treatment			

Topical antibiotics alone versus topical antibiotics plus systemic antibiotics:

See option on topical antibiotics plus systemic antibiotics in adults, p 14 .

Topical antibiotics plus topical corticosteroids:

See option on topical antibiotics plus topical corticosteroids in adults, p 3 .

Topical antibiotics added to tympanoplasty:

We found one RCT, which compared three interventions: preoperative topical ofloxacin instilled for 10 minutes, preoperative topical ofloxacin instilled for 3 minutes, and no preoperative topical treatment. [47]

Reduction in otorrhoea

Topical antibiotics added to tympanoplasty compared with no treatment Topical antibiotics added to tympanoplasty seem no more (or less) effective at closing tympanic perforations in adults about to have tympanoplasty (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Tympanic perforations					
[47] RCT **3-armed trial**	101 adults about to have tympanoplasty	**Closure of tympanic perforations** 28/33 (85%) with 10 minutes' ofloxacin 27/33 (82%) with 3 minutes' ofloxacin 31/35 (89%) with no treatment	Reported as no significant difference among groups P value not reported The RCT may have lacked power to detect clinically important differences	⟷	Not significant

Hearing

No data from the following reference on this outcome. [47]

Intra- and extracranial complications

No data from the following reference on this outcome. [47]

Death

No data from the following reference on this outcome. [47]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[47] RCT **3-armed trial**	101 adults about to have tympanoplasty	**Adverse effects** with 10 minutes' ofloxacin with 3 minutes' ofloxacin with no treatment No major adverse effects reported with topical ofloxacin			

Further information on studies

[32] The RCT lasted only 7 days, had 30% loss to follow-up (15/50), and did not describe the methods of randomisation and allocation concealment clearly.

Comment:

We identified one abstract describing one RCT (36 adults) comparing topical ciprofloxacin versus topical neomycin–polymyxin–fluocinolone (NPF); we were unable to obtain the full text of this Spanish-language paper to assess the quality of the study. [48] The abstract reported that the RCT found no significant difference in "good" treatment results (rated as "good", "regular", or "poor") between treatments after 10 days (85% with ciprofloxacin *v* 80% with NPF; P value not reported in abstract).

Clinical guide:

There is consensus that topical antibiotics must be combined with thorough ear cleansing to be effective. We found no evidence about the long-term effects of topical antibiotics on complications of chronic suppurative otitis media. We found no clear evidence from RCTs of ototoxicity associated with any topical antibiotic. Evidence about ototoxicity is based only on the assessment of audiograms after short-term exposure to antibiotics, and on case studies that have reported ototoxicity associated with some topical non-quinolone antibiotics for 7 to 120 days. [49] [50] [51] Most people in the observational studies had vestibular rather than cochlear symptoms, suggesting that the evidence from audiograms and hearing tests may not exclude ototoxicity. One review of case studies for ototoxicity found a total of 54 cases of gentamicin vestibular toxicity, and in 24 of those cases cochlear toxicity was also documented. [52] The review also found 11 cases of cochlear and two cases of vestibular toxicity for neomycin-based ear drops. [52] Most topical non-quinolone antibiotics have licence restrictions against prolonged use, or use in people with perforation of the eardrum.

OPTION ANTISEPTICS (TOPICAL) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical antiseptics are beneficial in reducing symptoms.

Benefits and harms

Topical antiseptics versus placebo:

We found no systematic review or RCTs comparing topical antiseptics versus placebo in adults with chronic suppurative otitis media.

Topical antiseptics versus topical antibiotics:

See option on topical antibiotics in adults, p 17 .

Topical antiseptics versus systemic antibiotics:

See option on systemic antibiotics in adults, p 8 .

Further information on studies

Comment: Topical antiseptics include aluminium acetate, borax, boric acid, hydrogen peroxide, and iodine powder. The available evidence in adults is insufficient to establish or exclude a clinically important effect from topical antiseptics.

OPTION CORTICOSTEROIDS (TOPICAL) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical corticosteroids are beneficial in reducing symptoms.

Benefits and harms

Topical corticosteroids versus placebo or no treatment:

We found no systematic review or RCTs.

Topical corticosteroids versus topical antibiotics plus topical corticosteroids:

See option on topical antibiotics plus topical corticosteroids in adults, p 3 .

Further information on studies

Comment: None.

OPTION EAR CLEANSING (AURAL TOILET) IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We found no clinically important results about ear cleansing compared with no treatment in adults with chronic suppurative otitis media.

Benefits and harms

Ear cleansing versus no treatment:

We found no systematic review, RCTs, or observational studies of sufficient quality comparing ear cleansing versus no treatment in adults.

Further information on studies

Comment: **Clinical guide:**
Techniques of ear cleansing vary considerably. In developed countries and advantaged populations, microsuction of the external and middle ear under microscopic control by a trained operator is the standard method of ear cleansing. Microscopic examination of the ear with ear cleansing is an important aspect of diagnosis of persistent otorrhoea. In developing countries and disadvantaged populations, otoscopic examination after dry mopping, ear wicking, and ear irrigation with sterile liquid is considered part of standard treatment.

OPTION TYMPANOPLASTY WITH OR WITHOUT MASTOIDECTOMY IN ADULTS

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether tympanoplasty with or without mastoidectomy improves symptoms compared with no surgery or other treatments in adults with chronic suppurative otitis media.

Benefits and harms

Tympanoplasty with or without mastoidectomy versus no surgery:

We found no systematic review or RCTs (see comment).

Tympanoplasty plus mastoidectomy versus tympanoplasty alone:

We found one RCT (68 people) comparing type 1 tympanoplasty plus cortical mastoidectomy versus type 1 tympanoplasty alone. [53] All operations were conducted by three surgeons. Follow-up assessment occurred at 3 and 6 months postoperatively.

Reduction in otorrhoea

Tympanoplasty plus mastoidectomy compared with tympanoplasty alone We don't know whether tympanoplasty plus mastoidectomy is more effective at increasing discharge resolution in adults at 3 months post surgery (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Reduction in otorrhoea					
[53] RCT	68 adults	**Proportion of people with residual perforation plus discharge , 3 months post surgery** 1/33 (3%) with type 1 tympanoplasty plus cortical mastoidectomy 3/35 (9%) with type 1 tympanoplasty alone	Reported as not significant P value not reported	⟷	Not significant

Hearing

Tympanoplasty plus mastoidectomy compared with tympanoplasty alone Tympanoplasty plus mastoidectomy seems as effective at improving hearing in adults at 3 months post surgery (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Hearing					
[53] RCT	68 adults	**Mean change in hearing level (dB) , 3 months post surgery** –4.8 dB with type 1 tympanoplasty plus cortical mastoidectomy –9.3 dB with type 1 tympanoplasty alone	P = 0.16	⟷	Not significant

Intra- and extracranial complications

No data from the following reference on this outcome. [53]

Death

No data from the following reference on this outcome. [53]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[53] RCT	68 adults	**Proportion of people with tympanosclerosis , postoperative follow-up** 2/35 (6%) with type 1 tympanoplasty plus cortical mastoidectomy 0/33 (0%) with type 1 tympanoplasty alone	P value not reported		

Further information on studies

[53] In their description of adverse events, the authors stated that there were two cases of tympanosclerosis (scarring of the tympanic membrane), but no other complications.

Comment: We found many retrospective cohort studies. One of these (41 adults with bilateral chronic suppurative otitis media operated on at one unit in Italy) compared hearing in ears that had had previous tympanoplasty versus hearing in contralateral ears treated without surgery. [54] The hearing in both operated and non-operated ears progressively deteriorated, but the rate of decline was significantly slower in operated ears.

Clinical guide:
Tympanoplasty can be combined with mastoidectomy when the possibility exists of restoring some functional hearing without jeopardising surgical clearance of the disease. Observational studies have found that the success of surgery depends on several factors: age, technical skill of the surgeon, [55] availability of remnant eardrum and ossicles, [56] and type of mastoidectomy performed. The success rate for sealing a tympanic perforation with a graft can be as high as 90% to 95%. Hearing deficit may be corrected in about 50% to 70% of operated ears. [57] [58] [59]

QUESTION What are the effects of treatments for chronic suppurative otitis media in children?

OPTION ANTIBIOTICS (SYSTEMIC) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether systemic antibiotics improve symptoms in children with chronic suppurative otitis media compared with placebo or other treatments.

Benefits and harms

Systemic antibiotics versus placebo or no antibiotics in children having no other treatment:

We found no systematic review or RCTs investigating the effects of systemic antibiotics in children receiving no other treatment.

Systemic antibiotics versus placebo or no treatment in children having ear cleansing and debridement:

We found one open-label RCT. [60]

Reduction in otorrhoea

Compared with placebo or no treatment Systemic antibiotics seem more effective at reducing persistent otorrhoea at 6 months in children with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[60] RCT **3-armed trial** Open label	33 children having ear cleansing by suctioning and debridement for 1 to 2 weeks (see further information on studies)	**Persistent otorrhoea detected at otoscopy , 6 months** 0/21 (0%) with intravenous antibiotic (mezlocillin or ceftazidime for 3–21 days) 11/12 (92%) with no antibiotic	P <0.01	○○○	intravenous antibiotic

Hearing

No data from the following reference on this outcome. [60]

Intra- and extracranial complications

No data from the following reference on this outcome. [60]

Death

No data from the following reference on this outcome. [60]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[60] RCT **3-armed trial** Open label	33 children having ear cleansing by suctioning and debridement for 1 to 2 weeks	**Adverse effects** with intravenous antibiotic (mezlocillin or ceftazidime for 3–21 days) with no antibiotic Absolute results not reported The RCT reported no worsening of hearing during or after the systemic antimicrobial treatment as measured by audiometry			

Systemic antibiotics versus each other:
We found two open-label RCTs. [60] [61]

Reduction in otorrhoea

Compared with each other We don't know which systemic antibiotic is more effective at reducing otorrhoea in children with chronic suppurative otitis media (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[60] RCT **3-armed trial** Open label	51 children randomised, 48 completed (see further information on studies). All children also had ear cleansing by suctioning and debridement for 1 to 2 weeks The remaining arm (12 children) assessed ear cleansing by suctioning and debridement alone (see further information on studies)	**Otoscopic evidence of otorrhoea** 0/17 (0%) with intravenous mezlocillin 0/19 (0%) with intravenous ceftazidime	Significance assessment not reported for intravenous mezlocillin *v* ceftazidime		
[61] RCT Open label	30 children	**Complete disappearance of discharge** 85% with intravenous ceftazidime 67% with oral aztreonam Absolute numbers not reported	P value reported as not significant	⟷	Not significant
[61] RCT Open label	30 children	**Days to disappearance of discharge** 7.9 days with intravenous ceftazidime 8.4 days with oral aztreonam	P value reported as not significant	⟷	Not significant

Hearing

No data from the following reference on this outcome. [60] [61]

Intra- and extracranial complications

No data from the following reference on this outcome. [60] [61]

Death

No data from the following reference on this outcome. [60] [61]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[60] RCT **3-armed trial**	51 children randomised, 48 completed (see further information on studies). All children also had ear cleansing by suctioning and debridement for 1 to 2 weeks Open label The remaining arm (12 children) assessed ear cleansing by suctioning and debridement alone (see further information on studies)	**Adverse effects** with intravenous mezlocillin with intravenous ceftazidime Absolute results not reported No worsening of hearing during or after the systemic antimicrobial treatment as measured by audiometry was reported			
[61] RCT	30 children Open label	**Adverse effects** with intravenous ceftazidime with oral aztreonam Absolute results not reported Ceftazidime and aztreonam were reported to be well tolerated			

Systemic antibiotics versus topical antibiotics:

See option on topical antibiotics in children, p 30 .

Systemic antibiotics versus topical antiseptics:

We found no systematic review or RCTs.

Further information on studies

[60] The first 33 children recruited in the study were randomly assigned to one of the three regimens (intravenous mezlocillin, intravenous ceftazidime, and no antibiotic) plus suction and debridement. Following analysis of results at 2 weeks, the no-antibiotic arm was discontinued; results are analysed only for 36 children who initially received antibiotics (17 mezlocillin, 19 ceftazidime).

Comment: We found no clear evidence from RCTs that different systemic antibiotics differ in their effectiveness. The studies in children found similar results to those in adults.

OPTION ANTIBIOTICS (TOPICAL) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical antibiotics improve symptoms in children with chronic suppurative otitis media compared with placebo or other treatments.
- Topical antibiotics improve resolution of ear discharge compared with topical antiseptics.
- The risk of ototoxicity associated with both topical treatments is unclear.

Benefits and harms

Topical antibiotics versus placebo or no treatment:

We found one systematic review (search date 2005), which found no RCTs solely in children. [43]

Topical antibiotics versus each other:

We found one systematic review (search date 2005), [43] which identified one RCT. [62] The RCT compared three treatments given three times daily for 2 weeks: 0.5% neomycin/0.1% polymyxin B, 0.3% ofloxacin, and antiseptic ear drops.

Reduction in otorrhoea

Compared with each other We don't know which topical antibiotic is more effective at increasing discharge resolution rates at 2 weeks in children with chronic suppurative otitis media (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[62] RCT **3-armed trial**	96 children in rural Malawi; 54 ears analysed In review [43] The remaining arm assessed antisep-tic ear drops	**Discharge resolution rates , 2 weeks** 3/14 (21%) with ofloxacin 7/40 (18%) with neomycin–polymyxin Suction cleaning was performed in all groups at the beginning and during the weekly visits	RR for ofloxacin *v* neomycin–polymyxin 1.22 95% CI 0.37 to 4.10	⟷	Not significant

Hearing

No data from the following reference on this outcome. [43] [62]

Intra- and extracranial complications

No data from the following reference on this outcome. [43] [62]

Death

No data from the following reference on this outcome. [43] [62]

Adverse effects

No data from the following reference on this outcome. [43] [62]

Topical antibiotics versus systemic antibiotics:

We found one systematic review (search date 2000), [63] which identified no RCTs solely in children with chronic suppurative otitis media.

Topical antibiotics versus topical antiseptics:

See option on topical antiseptics in children, p 34 .

Topical antibiotics versus topical antibiotics plus topical corticosteroids:

We found one RCT (97 children) [64] comparing topical ciprofloxacin (0.3%) 4 drops twice daily with topical framycetin–gramicidin–dexamethasone 4 drops twice daily.

Reduction in otorrhoea

Compared with topical antibiotics plus topical corticosteroids Topical antibiotics alone seem as effective at reducing persistent otorrhoea at 6 to 28 weeks in children with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Reduction in otorrhoea					
[64] RCT	97 Aboriginal children aged 1 to 15 years, in Australia, with persistent chronic suppurative otitis media (CSOM) despite previous treatment	**Proportion of children with persistent otorrhoea at end of treatment , 6 to 8 weeks** 35/50 (70%) with topical ciprofloxacin 0.3% 34/47 (72%) with topical framycetin–gramicidin–dexamethasone	Risk difference –2% 95% CI –20% to +16%	⟷	Not significant
[64] RCT	97 Aboriginal children aged 1 to 15 years, in Australia, with persistent CSOM despite previous treatment	**Proportion of children with persistent otorrhoea at follow-up , 12 to 28 weeks** 43/50 (86%) with topical ciprofloxacin 0.3%	Risk difference +12% 95% CI –4% to +27%	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		35/47 (74%) with topical framycetin–gramicidin–dexamethasone			
[64] RCT	97 Aboriginal children aged 1 to 15 years, in Australia, with persistent CSOM despite previous treatment	**Proportion of children with persistent perforation at end of treatment , 6 to 8 weeks** 49/50 (98%) with topical ciprofloxacin 0.3% 47/47 (100%) with topical framycetin–gramicidin–dexamethasone	Risk difference –2% 95% CI –6% to +2%	⟷	Not significant

Hearing

Compared with topical antibiotics plus topical corticosteroids Topical antibiotics alone seem as effective at improving hearing threshold at 4 to 7 months in children with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Hearing					
[64] RCT	97 Aboriginal children aged 1 to 15 years, in Australia, with persistent chronic suppurative otitis media (CSOM) despite previous treatment	**Mean hearing threshold at follow up , 4 to 7 months** 38 dB with topical ciprofloxacin 0.3% 35 dB with topical framycetin–gramicidin–dexamethasone Analysis includes 41 children with ciprofloxacin and 32 children with framycetin–gramicidin–dexamethasone	Mean difference +3 dB 95% CI –1 dB to +6 dB	⟷	Not significant

Intra- and extracranial complications

No data from the following reference on this outcome. [64]

Death

No data from the following reference on this outcome. [64]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[64] RCT	97 Aboriginal children aged 1 to 15 years, in Australia, with persistent chronic suppurative otitis media	**Proportion of children withdrawn from study owing to adverse events by end of treatment , 6 to 8 weeks** 0/50 (0%) with topical ciprofloxacin 0.3%	P value not reported		

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	(CSOM) despite previous treatment	0/47 (0%) with topical framycetin–gramicidin–dexamethasone			

Further information on studies

[62] [43] The RCT identified by the systematic review was published in abstract form and described briefly in a later publication. [65] Details of the methodology were not clearly reported. Follow-up was short and the sample size small, suggesting that important differences might not be detected.

[64] This RCT used allocation concealment and standardised assessment by a blinded outcome assessor. Analysis was by modified intention to treat where all children not seen were categorised as clinical failures. Clinical assessment was possible in 89 children (92%) at end of treatment (6–8 weeks after randomisation) and in 90 children (93%) at follow-up (12–28 weeks after randomisation).

Comment: **Clinical guide:**
We found no RCTs fully evaluating the risk of ototoxicity from any topical antibiotic in children. Evidence about ototoxicity is based on the assessment of audiograms after short-term exposure to the antibiotics. Uncontrolled case studies have reported ototoxicity associated with use of some topical non-quinolone antibiotics for 7 to 120 days. [49] [50] [51] Most people in the observational studies had vestibular rather than cochlear symptoms, suggesting that the evidence from audiograms and hearing tests may not exclude ototoxicity. Most topical non-quinolone antibiotics have licence restrictions against prolonged use or use in people with perforation of the eardrum. See also comment on ear cleansing in children, p 38 .

OPTION ANTIBIOTICS (TOPICAL) PLUS CORTICOSTEROIDS (TOPICAL) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical corticosteroids in combination with antibiotics improve symptoms in children with chronic suppurative otitis media compared with placebo or other treatments.

Benefits and harms

Topical antibiotics plus topical corticosteroids:

We found no RCTs comparing topical antibiotics plus topical corticosteroids versus placebo.

Topical antibiotics plus topical corticosteroids versus topical antibiotics alone:

See option on topical antibiotics in children, p 30 .

Further information on studies

Comment: We found no RCTs or systematic reviews about long-term effects on complications. See comment on topical antibiotics in children, p 30 .

OPTION ANTISEPTICS (TOPICAL) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical antiseptics improve symptoms in children with chronic suppurative otitis media compared with placebo or other treatments.
- Topical antibiotics improve resolution of ear discharge compared with topical antiseptics. The risk of ototoxicity associated with both topical treatments is unclear.

Benefits and harms

Topical antiseptics versus placebo or no treatment:

We found no systematic review but found two RCTs. [66] [67] The first RCT compared aluminium acetate solutions of varying concentrations (13.00% *v* 3.25% *v* 1.30%). [66] The second RCT compared 5 interventions: ear cleansing alone, ear cleansing plus topical antiseptic, ear cleansing plus topical antiseptic plus topical antibiotics plus topical corticosteroid, ear cleansing plus topical antiseptic plus topical antibiotics plus topical corticosteroid plus oral antibiotic (clindamycin), and no treatment. [67]

Reduction in otorrhoea

Compared with placebo or no treatment We don't know whether topical antiseptics are more effective at reducing otorrhoea at 2 to 6 weeks in children with chronic suppurative otitis media (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[66] RCT **3-armed trial**	60 children with otorrhoea in a hospital clinic in South Africa, 67 ears; results were obtained for 56/67 (84%) ears	**Dry ears , 2 weeks** 21/26 (81% of ears) with aluminium acetate 13% 15/20 (75% of ears) with aluminium acetate 3.25% 5/10 (50% of ears) with aluminium acetate 1.3% The most dilute solution was considered to be inactive	P = 0.18 The RCT may have lacked power to detect a clinically important difference	⟷	Not significant
[67] RCT **5-armed trial**	134 children, 180 ears; 43 children, 58 ears in this analysis The remaining arms assessed: ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid, ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid plus oral antibiotic (clindamycin), and no treatment	**Proportion of children with unchanged otoscopic appearance , 6 weeks** 12/32 (38%) with ear cleansing plus topical antiseptic (boric acid 2% in 20% alcohol, 3 drops to each ear, 4 times daily after ear cleansing) 13/26 (50%) with ear cleansing alone	OR for ear cleansing plus topical antiseptic *v* ear cleansing alone 0.61 95% CI 0.22 to 1.71	⟷	Not significant

Hearing

No data from the following reference on this outcome. [66] [67]

Intra- and extracranial complications

No data from the following reference on this outcome. [66] [67]

Death

No data from the following reference on this outcome. [66] [67]

Adverse effects

No data from the following reference on this outcome. [66] [67]

Topical antiseptics versus topical antibiotics:

We found one systematic review (search date 2005; 3 RCTs). [43] The first RCT identified by the review compared topical boric acid (2% in 45% alcohol) versus topical ciprofloxacin (0.3%). [68] The second RCT identified by the review compared three treatments, given three times daily for 2 weeks: topical antiseptic (acetic acid 2% in 25% spirit and glycerin 30%), neomycin 0.5%/polymyxin B 0.1%, and ofloxacin 0.3%. [62] The third RCT identified by the review compared three treatments: a single application of ofloxacin 0.075% in hydroxypropyl methylcellulose (HPMC) 1.5%, povidone iodine 1% in HPMC 1.5%, and HPMC 1.5% alone (placebo), as single applications.

Reduction in otorrhoea

Compared with topical antibiotics Topical antiseptics seem less effective at reducing persistent discharge at 1 to 4 weeks in children with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[68] RCT	427 African school children In review [43]	**Persistent discharge , at 4 weeks** 66/196 (34%) with topical ciprofloxacin (0.3%) 108/198 (54%) with topical boric acid (2% in 45% alcohol)	RR 0.62 95% CI 0.49 to 0.78	●○○	topical ciprofloxacin
[62] RCT **3-armed trial**	96 children randomised; 93 ears in 69 children analysed In review [43]	**Persistent discharge , 2 weeks** 3/14 (21%) with ofloxacin 0.3% 7/40 (17%) with neomycin 0.5%/polymyxin B 0.1% 34/39 (87%) with topical antiseptic (2% acetic acid in 25% spirit and 30% glycerin) Suction cleaning was performed in all groups at the beginning and during the weekly visits	RR for ofloxacin *v* antiseptic 0.25 95% CI 0.09 to 0.68 RR for neomycin–polymyxin B *v* antiseptic 0.20 95% CI 0.10 to 0.40	●●○	topical antibiotics (ofloxacin or neomycin–polymyxin B)
[43] Systematic review **3-armed trial**	253 ears Data from 1 RCT The remaining arm assessed hydroxypropyl methylcellulose (HPMC) 1.5% alone (placebo)	**Persistent discharge , 1 week** 32/79 (40%) with ofloxacin 0.075% in HPMC 1.5% 77/91 (85%) with povidone iodine 1% in HPMC 1.5% Single applications	RR for ofloxacin *v* povidone iodine 0.52 95% CI 0.41 to 0.67	●○○	topical ofloxacin

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Tympanic perforations					
[68] RCT	427 African school children In review [43]	**Healing of tympanic perforations , 2 weeks** 15/207 (7.2%) with topical ciprofloxacin (0.3%) 14/204 (6.9%) with topical boric acid (2% in 45% alcohol)	RR 1.06 95% CI 0.52 to 2.13	⟷	Not significant
[68] RCT	427 African school children In review [43]	**Healing of tympanic perforations , 4 weeks** 31/200 (15%) with topical ciprofloxacin (0.3%) 20/199 (10%) with topical boric acid (2% in 45% alcohol)	RR 1.54 95% CI 0.91 to 2.61	⟷	Not significant

Hearing

Compared with topical antibiotics Topical antiseptics seem less effective at improving hearing at 2 to 4 weeks in African school children with chronic suppurative otitis media (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Hearing					
[68] RCT	427 African school children In review [43]	**Mean decibel improvement , 2 weeks** 4.32 dB with topical ciprofloxacin (0.3%) 2.69 dB with topical boric acid (2% in 45% alcohol)	Difference 2.17 dB 95% CI 0.09 dB to 4.24 dB P = 0.041 Clinical importance of this improvement unclear	○○○	topical ciprofloxacin
[68] RCT	427 African school children In review [43]	**Mean decibel improvement , 4 weeks** 5.42 dB with topical ciprofloxacin (0.3%) 2.63 dB with topical boric acid (2% in 45% alcohol)	Difference 3.43 dB 95% CI 1.34 dB to 5.52 dB P = 0.001 Clinical importance of this improvement unclear	○○○	topical ciprofloxacin

No data from the following reference on this outcome. [62]

Intra- and extracranial complications

No data from the following reference on this outcome. [43] [62] [68]

Death

No data from the following reference on this outcome. [43] [62] [68]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[68] RCT	427 African school children In review [43]	**Adverse effects (ear pain, irritation, and bleeding on ear mopping combined)** 17/210 (8%) with topical ciprofloxacin 30/206 (15%) with topical boric acid (antiseptic)	ARR 7% 95% CI 0.3% to 13%	⟷	Not significant

No data from the following reference on this outcome. [43] [62]

Topical antiseptics versus topical antibiotic plus corticosteroid:

We found no RCTs.

Topical antiseptics versus systemic antibiotics:

See option on systemic antibiotics in children, p 27 .

Further information on studies

[62] The RCT is an unpublished study that did not clearly report its methods and had a small sample size.

[67] The RCT is susceptible to bias. It was performed in an area with a high prevalence of chronic suppurative otitis media (CSOM) (Solomon Islands). It followed all the randomised children for 6 weeks but presented results as number of ears with persistent otorrhoea. It did not describe allocation concealment or blinding methods.

[68] The RCT enforced allocation concealment and blinded participants, carers, and outcome assessors to the treatment allocated throughout the study.

Comment: The available evidence suggests that topical antiseptics are less effective than topical antibiotics, particularly topical quinolones, in the short-term resolution of ear discharge. See also comment on ear cleansing in children, p 38 .

OPTION CORTICOSTEROIDS (TOPICAL) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether topical corticosteroids alone improve symptoms in children with chronic suppurative otitis media compared with placebo or other treatments.

Benefits and harms

Topical corticosteroids versus placebo or no treatment:

We found no systematic review or RCTs.

Further information on studies

Comment: None.

OPTION EAR CLEANSING (AURAL TOILET) IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- In children with chronic suppurative otitis media, the benefits of ear cleansing are unknown, although this treatment is usually recommended for children with ear discharge.

Benefits and harms

Ear cleansing versus no treatment:

We found two RCTs. [67] [69] The first RCT compared 5 interventions: ear cleansing alone, ear cleansing plus topical antiseptic, ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid (topical dexamethasone 0.05%, framycetin sulphate 0.5%, and gramicidin 0.005%), ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid plus oral antibiotic (clindamycin), and no treatment. [67] The second RCT compared three treatments: ear cleansing (dry mopping) alone, ear cleansing (dry mopping) plus topical antibiotics plus topical corticosteroids plus systemic antibiotics, and no treatment. [69] We found no observational studies of ear cleansing that were of sufficient quality.

Reduction in otorrhoea

Compared with no treatment We don't know whether ear cleansing is more effective at drying or healing perforations at 6 to 16 weeks in children with chronic suppurative otitis media (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Otorrhoea					
[67] RCT **5-armed trial**	134 children The remaining arms assessed: ear cleansing plus topical antiseptic, ear cleansing plus topical antiseptic plus topical antibiotics plus topical corticosteroid, ear cleansing plus topical antiseptic plus topical antibiotics plus topical corticosteroid plus oral antibiotic (clindamycin)	**Proportion of improved ears (dry or healed perforations) , 6 weeks** 50% with ear cleansing 18% with no treatment Absolute numbers not reported	P <0.01 for ear cleansing *v* no treatment	○○○	ear cleansing
[69] RCT **3-armed trial**	524 children The remaining arm assessed ear cleansing (dry mopping) plus topical antibiotics plus topical corticosteroids plus systemic antibiotics	**Resolution of chronic suppurative otitis media , 16 weeks** 23% with ear cleansing 22% with no treatment Absolute numbers not reported	Reported as not significant for ear cleansing *v* no treatment P value not reported	⟷	Not significant
Perforated eardrum					
[69] RCT **3-armed trial**	524 children The remaining arm assessed ear cleansing (dry mopping) plus topical antibiotics plus topical corticos-	**Healing of perforated eardrums , 16 weeks** 13% with ear cleansing alone 13% with no treatment Absolute numbers not reported	Reported as not significant for ear cleansing *v* no treatment P value not reported	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	teroids plus systemic antibiotics				

Hearing

No data from the following reference on this outcome. [67] [69]

Intra- and extracranial complications

No data from the following reference on this outcome. [67] [69]

Death

No data from the following reference on this outcome. [67] [69]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[69] RCT **3-armed trial**	524 children The remaining arm assessed ear cleansing (dry mopping) plus topical antibiotics plus topical corticosteroids plus systemic antibiotics	**Adverse effects** with ear cleansing alone with no treatment Absolute results not reported No evidence of ototoxicity associated with the treatments and no symptoms or complaints suggesting ototoxicity were noted among participants			

No data from the following reference on this outcome. [67]

Further information on studies

[67] The RCT is susceptible to bias. It was performed in an area with a high prevalence of chronic suppurative otitis media (CSOM) (Solomon Islands). It followed all the randomised children for 6 weeks but presented results as number of ears with persistent otorrhoea. It did not describe allocation concealment or blinding methods.

[69] The RCT is susceptible to bias. It was performed in an area with a high prevalence of CSOM (Kenya). It randomised 145 schools but analysed the numbers of children with persistent otorrhoea. It followed children for 16 weeks but analysed results only for the 72% of the children who completed the RCT. In this RCT, the randomisation process was concealed, but outcome assessors were not blinded to treatment allocation.

Comment:

Clinical guide:
Techniques of ear cleansing vary considerably. In some countries, microsuction of the external and middle ear under microscopic control by a trained operator is a standard method of ear cleansing. In other countries, cleansing of the external auditory canal may be performed by parents, carers, or peers by dry mopping with tissue paper spears or with cotton wool on thin wooden sticks. This is done from two to four times daily. Ear cleansing is usually considered as an integral part of any intervention for chronic persistent otorrhoea. When combined with a topical treatment, the aim is to ensure that the medication is able to reach the middle ear space. Almost all the RCTs included in this review incorporated ear cleansing in the trial arms. Overall, we found no good evidence of benefit from simple ear cleansing alone, but the evidence is not strong enough to exclude a clinically important benefit.

OPTION TYMPANOPLASTY WITH OR WITHOUT MASTOIDECTOMY IN CHILDREN

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether tympanoplasty with or without mastoidectomy improves symptoms compared with no surgery or other treatments in children with chronic suppurative otitis media (CSOM).
- We found no clinically important results from RCTs about tympanoplasty with or without mastoidectomy compared with no surgery in children with CSOM without cholesteatoma.

Benefits and harms

Tympanoplasty with or without mastoidectomy versus no surgery:

We found no systematic review or RCTs.

Further information on studies

Comment:

We found no evidence from RCTs, but we found numerous retrospective observational studies. Tympanoplasty is often combined with mastoidectomy whenever the possibility exists of restoring some functional hearing without jeopardising surgical clearance of the disease. Observational studies have found that the success of surgery depends on several factors (age, technical skill of the surgeon, [70] presence of middle-ear discharge, [71] type of mastoidectomy performed, and technique of middle-ear construction [55]). Success rate for sealing a tympanic perforation with a graft can be 90% to 95%. Hearing deficit may be corrected in about 50% to 70% of operated ears. [57] [58] [59] Long-term prospective follow-up of a high-risk population (93 Aboriginal children) that received tympanoplasty (6% also received mastoidectomy) found that, at median follow-up of 103 months after tympanoplasty, 56/93 (60%) had intact tympanic membranes and normal hearing, whereas 17/93 (18%) did not. [72]

QUESTION What are the effects of treatments for cholesteatoma in adults?

OPTION SURGERY FOR CHOLESTEATOMA IN ADULTS New

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether surgery (early or delayed), or which surgical techniques, improve symptoms in adults with cholesteatoma.

Benefits and harms

Surgery for cholesteatoma:

We found no systematic review or RCTs.

Further information on studies

Comment: We found no evidence from RCTs, but we found one prospective controlled non-randomised study of the ancillary use of the KTP (potassium titanyl phosphate) laser compared with intact canal wall cholesteatoma surgery alone. [73] This study described a large difference (3% with KTP laser *v* 30% with cholesteatoma surgery) in residual disease present at the second-stage operation (at least 12 months after the initial surgery). [73]

QUESTION What are the effects of treatments for cholesteatoma in children?

OPTION SURGERY FOR CHOLESTEATOMA IN CHILDREN New

- For GRADE evaluation of interventions for Chronic suppurative otitis media, see table, p 44 .
- We don't know whether surgery (early or delayed), or which surgical techniques, improve symptoms in children with cholesteatoma.

Benefits and harms

Surgery for cholesteatoma:

We found no systematic review or RCTs.

Further information on studies

Comment: Cholesteatoma in children can be either congenital or acquired.

GLOSSARY

Ear cleansing Also known as aural toilet, this consists of mechanical removal of ear discharge and other debris from the ear canal and middle ear by mopping with cotton pledgets, wicking with gauze, flushing with sterile solution, or suctioning. This can be done with an otomicroscope or under direct vision with adequate illumination of the middle ear.

Mastoidectomy A general term used to describe various surgical procedures that are usually used to remove abnormal parts of the mastoid bone and surrounding structures, or to allow access to the middle ear.

Tympanoplasty A general term used to describe various surgical repairs of the eardrum or ossicles of the middle ear to improve hearing in people with conductive deafness.

Cholesteatoma An accumulation of epithelial debris in the middle ear cavity, which can arise congenitally or can be acquired. The tissue is probably derived from skin. It grows slowly but can erode and destroy adjacent structures (ossicles, the mastoid, the inner ear, or the bone leading to the intracranial cavity), potentially leading to persistent pain and otorrhoea, hearing loss, dizziness, facial nerve paralysis, and intracranial infection.

Disability-adjusted life year (DALY) A measure of the impact of a condition, designed to include the loss attributable to premature death and the loss caused by a disability of known duration and severity. One DALY is equivalent to the loss of 1 year of healthy life.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Surgery for cholesteatoma in adults No systematic review or RCTs were found assessing the effects of surgery for cholesteatoma in adults. Categorised as Unknown effectiveness.

Surgery for cholesteatoma in children No systematic review or RCTs were found assessing the effects of surgery for cholesteatoma in children. Categorised as Unknown effectiveness.

Antibiotics (topical) in children New evidence added. [64] Categorisation unchanged (Unknown effectiveness) as there remains insufficient good-quality evidence to assess the effects of topical antibiotics in children with chronic suppurative otitis media.

Antibiotics (topical) plus corticosteroids (topical) in children New evidence added. [64] Categorisation unchanged (Unknown effectiveness).

Tympanoplasty with or without mastoidectomy in adults New evidence added. [53] Conclusions unchanged (Unknown effectiveness).

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Competing interests: PM declares that he has no competing interests.

Disclaimer

GRADE **Evaluation of interventions for Chronic suppurative otitis media.**

Important outcomes	Death, Hearing, Intra- and extracranial complications, Reduction in otorrhoea								
Studies (Participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of treatments for chronic suppurative otitis media in adults?									
2 (154) [24] [25]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids versus placebo	4	–1	0	–1	0	Low	Quality point deducted for sparse data. Directness point deducted for uncertainty about benefit
1 (64) [26]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids versus topical corticosteroids alone	4	–3	0	0	+1	Low	Quality points deducted for sparse data, no intention-to-treat analysis, and uncertainty about blinding. Effect-size point added for RR <0.5
2 (402) [28] [29]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids versus topical antibiotics alone	4	–1	0	–1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of outcome
5 (247) [30] [31] [32] [33] [34] [35]	Reduction in otorrhoea	Systemic antibiotics versus topical antibiotics	4	0	0	–1	0	Moderate	Directness point deducted for wide range of comparators
1 (51) [31]	**Reduction in otorrhoea**	Systemic antibiotics versus topical antiseptics	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
3 (286) [36] [37] [38]	Reduction in otorrhoea	Systemic antibiotics versus each other	4	0	–1	0	0	Moderate	Consistency point deducted for conflicting results
1 (26) [39]	Reduction in otorrhoea	Systemic antibiotics added to mastoidectomy or tympanoplasty	4	–1	0	–1	0	Low	Quality point deducted for sparse data. Directness point deducted for baseline differences in disease severity
3 (150) [32] [40] [41]	Reduction in otorrhoea	Topical plus systemic antibiotics versus topical antibiotics alone	4	–1	–1	–1	0	Very low	Quality point deducted for sparse data. Consistency point deducted for conflicting results. Directness point deducted for wide range of comparators
2 (308) [32] [42]	Reduction in otorrhoea	Topical antibiotics plus systemic antibiotics versus systemic antibiotics alone	4	–1	–1	0	0	Low	Quality point deducted for incomplete reporting of results. Consistency point deducted for conflicting results
1 (35) [32]	Reduction in otorrhoea	Topical antibiotics versus placebo	4	–3	0	0	0	Very low	Quality points deducted for sparse data and methodological issues (poor follow-up, and uncertainty about randomisation and blinding)
at least 4 (at least 402) [43]	Reduction in otorrhoea	Topical antibiotics versus each other	4	0	–1	0	0	Moderate	Consistency point deducted for conflicting results
2 (89) [31] [46]	Reduction in otorrhoea	Topical antibiotics versus topical antiseptics	4	–1	–1	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for conflicting results
1 (101) [47]	Reduction in otorrhoea	Topical antibiotics added to tympanoplasty	4	–1	0	0	0	Moderate	Quality point deducted for sparse data

Important outcomes	Death, Hearing, Intra- and extracranial complications, Reduction in otorrhoea								
Studies (Participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
1 (68) [53]	Reduction in otorrhoea	Tympanoplasty plus mastoidectomy versus tympanoplasty alone	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (68) [53]	Hearing	Tympanoplasty plus mastoidectomy versus tympanoplasty alone	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
What are the effects of treatments for chronic suppurative otitis media in children?									
1 (33) [60]	Reduction in otorrhoea	Systemic antibiotics versus placebo or no treatment in children having ear cleansing and debridement	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
2 (63) [60] [61]	Reduction in otorrhoea	Systemic antibiotics versus each other	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (96) [62]	Reduction in otorrhoea	Topical antibiotics versus each other	4	–3	0	0	0	Very low	Quality points deducted for sparse data and methodological issues (uncertainty about methodology and short follow-up)
1 (97) [64]	Reduction in otorrhoea	Topical antibiotics versus topical antibiotics plus topical corticosteroids	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
1 (73) [64]	Hearing	Topical antibiotics versus topical antibiotics plus topical corticosteroids	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
2 (103) [66] [67]	Reduction in otorrhoea	Topical antiseptics versus placebo or no treatment	4	–2	0	0	0	Low	Quality points deducted for sparse data and for 1 study being underpowered
3 (666) [43] [68] [62]	Reduction in otorrhoea	Topical antiseptics versus topical antibiotics	4	–1	0	0	0	Moderate	Quality point deducted for uncertainty about methodology in 1 study
1 (427) [68]	Hearing	Topical antiseptics versus topical antibiotics	4	0	0	–1	0	Moderate	Directness point deducted for uncertainty about clinical significance of difference in hearing outcome
2 (658) [67] [69]	Reduction in otorrhoea	Ear cleansing versus no treatment	4	–2	–1	0	0	Very low	Quality points deducted for allocation and blinding flaws. Consistency point deducted for conflicting results

We initially allocate 4 points to evidence from RCTs, and 2 points to evidence from observational studies. To attain the final GRADE score for a given comparison, points are deducted or added from this initial score based on preset criteria relating to the categories of quality, directness, consistency, and effect size. Quality: based on issues affecting methodological rigour (e.g., incomplete reporting of results, quasi-randomisation, sparse data [<200 people in the analysis]). Consistency: based on similarity of results across studies. Directness: based on generalisability of population or outcomes. Effect size: based on magnitude of effect as measured by statistics such as relative risk, odds ratio, or hazard ratio.